Remarks

Claims 26, 27, 29 and 42-45 are pending in the subject application. By this Amendment, Applicants have amended claims 26, 27, 29, 42 and 43 and added new claims 46-55. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, the original claims of the PCT pamphlet and the as-filed specification at page 5, lines 20-25). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 26, 27, 29 and 42-55 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 26, 27 and 29 are provisionally rejected for obviousness-type double patenting over claims 23-25, 37-42, 44, 46-55, 57, 59-60 and 63-65 of co-pending application 10/738,123. Applicants note that the '123 application has been allowed and will file a terminal disclaimer over the application once the patent number for that application is known. Accordingly, Applicants respectfully request that the requirement for the filing of the terminal disclaimer in this matter be held in abeyance until such time as the patent number for the '123 application is known.

Claims 26-27, 29 and 42-45 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Office Action indicates that claims 27 and 42 recite the term "derivative" which is not defined in the specification. By way of this Amendment, this term has been deleted from the claims. However, Applicants note that the term "derivative" relates to, for example, human monoclonal antibodies and/or recombinantly produced antibodies such as humanized or chimeric antibodies (see original claims 5 and 7 of the PCT pamphlet) and such antibodies are recited in the presently pending claims (see claim 26). The Office Action states that claims 27 and 29 lack proper antecedent basis. By this Amendment, the preamble in the claims has been changed to "labeled angiogenesis inhibiting molecule" thereby rendering this issue moot. In claim 26, "the same specificity" lacks antecedent basis and is not clear what is intended as encompassed by "the" specificity. In this regard, Applicants submit that the claim is clear to those skilled in the art who would interpret the claim as having the same specificity for JAM-C as the H33 antibody because of shared CDRs. Should the Examiner have preferred language in this regard, the undersigned would appreciate discussing this issue in order to arrive at satisfactory language. Accordingly,

reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 26-27, 29 and 42-49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. In an effort to expedite prosecution, Applicants' undersigned representative hereby submits a deposit declaration indicating that the deposited material, hybridoma 13H33, was accepted for deposit with the Deutsch Sammlung von Mikroorganismen und Zellkulturen GmbH on October 22, 2003 (ATCC Designation No. DSM ACC2622) under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure (*e.g.*, see 961 OG 21, 1977) and that all restrictions on the availability to the public of the materials so deposited will be irrevocably removed upon the granting of a patent disclosing the deposit. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 26-27, 29, and 42-45 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office Action argues that the scope of the claims includes a genus of H33 antibodies (*i.e.*, derivatives and/or a single domain antigen binding fragment) that is highly variable. However, it is respectfully submitted that the amendments made to the claims have rendered this issue moot and reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 26-27, 29, and 42-45 are rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. The Office Action indicates that the subject specification is enabled for a labeled angiogenesis inhibiting molecule and a method of binding an angiogencsis inhibiting molecule to JAM-C comprising a label and an angiogenesis inhibiting molecule but is not enabled for a derivative and/or single domain antigen-binding fragment of the H33 antibody.

Applicants respectfully assert that the claims as filed are enabled. However, as noted above, it is respectfully submitted that this issue is now moot in view of the amendments made to the claims. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 26, 29 and 42-45 are rejected under 35 U.S.C. § 102(b) as anticipated by Aurrand-Lions *et al.* (2001) in light of Bazzoni (2003). The Office Action asserts that Aurrand-Lions *et al.* disclose a rat monoclonal antibody specific for JAM-C, in light of Bazzoni, including the 13H33 monoclonal antibody. Applicants respectfully assert that the Aurrand-Lions *et al.* reference does not anticipate the claimed invention as the reference is not enabling because it fails to put the public in possession of the starting materials for the manufacture of the H33 antibody or the hybridoma producing the H33 antibody. Applicants also note that the Office Action has required a deposit and a deposit statement for the 13H33 hybridoma and antibody produced thereby on the basis that "it is unclear if cell lines which produce antibodies having the exact chemical identity of the antibodies designated H33 produced by the hybridoma 13H33 are known and publicly available, or can be reproducibly isolated without undue experimentation."

As the Patent Office is aware, the mere written description of a biological material does not normally enable a person skilled in the art to reproduce a specific, claimed biological material. *In re LeGrice*, 301 F.2d 929, 133 U.S.P.Q. 365 (1962)(holding that a mere written description of a "rose floribunda plant" would not normally enable a person skilled in the art to reproduce the plant, since plant breeders "are not presently able to control the factors which govern the combination of genes and chromosomes required to produce a new plant having certain predetermined desired properties"; that "[s]hould a plant variety become extinct one cannot deliberately produce a duplicate even though its ancestry and the techniques of cross-pollination be known"; and that the prior publication did not meet the legal requirements for the bar stated in *35 U.S.C.A. § 102(b)* as it did not communicate where the necessary starting material could be obtained).

Applicants further submit that the holding in *LeGrice* is not limited to plant materials. *Ex parte Argoudelis* (157 U.S.P.Q. 437, 440 (Pat. & Trademark Office Bd. App. 1967), rev'd on other grounds, 58 C.C.P.A. 769, 434 F.2d 1390 (1970)) applied the *LeGrice* holding to claims directed to an isolated antibiotic and methods of making an antibiotic produced by a strain of microorganism

and a reference asserted to anticipate the claimed invention. As stated by the Board of Appeals in that decision (regarding the publication cited as prior art), "It cannot be denied that *In re LeGrice* applies to the publication cited in this application to the same extent that it applied to the publications cited in that case. Moreover, we have ourselves held that a written description of the character involved in a case such as the present one is not sufficient to enable a person skilled in the art to produce the invention."

Finally, it is also respectfully submitted that the Court of Appeals for the Federal Circuit has also held that the disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (holding that "[w]ithout a disclosure enabling one skilled in the art to produce a transgenic mouse without undue experimentation, the reference would not be applicable as prior art). Accordingly, it is respectfully submitted that the cited reference does not meet the requirements of 35 U.S.C. § 102(b) for rejecting the present claims as the reference is not sufficient to enable one skilled in the art to produce the claimed invention and reconsideration and withdrawal of the rejection is respectfully requested.

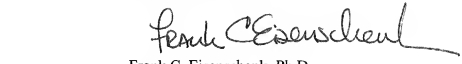
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/jb/sl
Attachment: Declaration of Frank C. Eisenschenk, Ph.D.